

Patent Cases To Watch In 2022

By **Dani Kass**

Law360 (January 3, 2022, 12:02 PM EST) -- The U.S. Supreme Court may consider whether a car part is a law of nature that can't be patented, and multiple courts are mulling the extent of the Patent Trial and Appeal Board's discretionary powers. Here's what you need to know about these and other high-profile patent cases.

American Axle v. Neapco

Every year, the Supreme Court gets petition upon petition asking it to tackle the state of patent eligibility under Section 101 of the Patent Act, and every year, it **refuses**. But with judges taking different views on how to interpret high court precedent on the topic, attorneys think American Axle may be the case that finally draws the justices in.

American Axle is a Federal Circuit decision invalidating a driveshaft patent for claiming a law of nature, which bitterly divided the full court during en banc petitioning. The circuit judges voted 6-6 over taking the case up and issued more than 100 pages of opinions, ultimately leaving the panel decision in place. American Axle appealed, and the justices in May asked for the solicitor general to weigh in on the case. The court is still awaiting that brief.

"Whereas most Section 101 cases involve software or a business method or something intangible, the American Axle claims are more physical," said Andrew Thomases of Ropes & Gray LLP.

Mintz Levin Cohn Ferris Glovsky and Popeo PC's Michael Renaud called American Axle "a monster case" that improperly expanded the Supreme Court's 2014 decision in *Alice Corp. v. CLS Bank*, which bars the patenting of abstract ideas unless they have an added inventive concept.

"Hundreds of thousands of U.S. patents have effectively been rendered not valuable by the holding in *Alice*, and American Axle threatens to spread that contagion to non-software patents," Renaud said. "If the Supreme Court doesn't take it up or takes it up and rules in favor of invalidating the patent, then you have a big change in the perception of what you can do with 101 challenges and *Alice*."

Meredith Addy of AddyHart PC likewise is unhappy with the decision in American Axle, but she said it'd be best if the Supreme Court doesn't take it up and the Federal Circuit instead acted on its patent law responsibilities to come up with cohesive rulings on patent eligibility.

"Every time they take something having to do with 101, they make it worse," Addy said of the justices. "I

don't believe we can rely on the Supreme Court in this area. I would love if the Federal Circuit would take a case such as American Axle — which they missed their opportunity on — and go en banc and say, 'This is the state of the law.' They can do that, but they have been punting to the Supreme Court."

Axinn Veltrop & Harkrider LLP's Jeannine Sano noted that the Supreme Court lineup has changed enough in recent years that it's possible the pattern of not taking up eligibility cases will come to an end this term.

The case is American Axle & Manufacturing Inc. v. Neapco Holdings LLC, case number 20-891, in the Supreme Court of the United States.

PersonalWeb v. Patreon

The justices have also asked for the solicitor general's take on another patent case — one involving the interpretation of a doctrine established by the 1907 Supreme Court case Kessler v. Eldred. The Kessler doctrine holds that a defeated party in an infringement suit can't bring follow-up litigation based on the same invention against the winning party's customers.

Software developer PersonalWeb is hoping to bring a suit against Amazon's customers after dropping litigation against Amazon with the same allegations. PersonalWeb says the voluntary dismissal means the Kessler doctrine doesn't apply, and argues that the doctrine creates special rules for patent cases — a practice the Supreme Court tends to disfavor.

This patent exceptionalism argument is why Addy thinks this case is likely to be taken up by the justices.

"It looks like the Federal Circuit is creating its own kind of patent-specific rule, and the Supreme Court hates that," she said.

Ropes & Grays' Thomases said the case invokes a very "specific factual pattern," but that it could have broader implications when plaintiffs sue both a manufacturer and a reseller.

The case is PersonalWeb Technologies LLC v. Patreon Inc. et al., case number 20-1394, in the Supreme Court of the United States.

Apple v. Hirshfeld, Apple v. Optis, Mylan v. Janssen and Intel v. VLSI

2022 will likely be the year attorneys see whether Patent Trial and Appeal Board policy — in the form of the U.S. Patent and Trademark Office director making cases precedential — can be challenged. More specifically, various companies are challenging Fintiv, which is a piece of PTAB precedent that allows the board's judges to turn away patent validity challenges they believe have merit because another venue, such as a district court, may decide the case first.

The major district court suit came from Apple, Google, Cisco, Intel and Edwards Lifesciences, which were challenging the policy under the Administrative Procedures Act. However, a California federal judge **dismissed it** in November, saying that the companies are appealing a PTAB institution decision, which under the America Invents Act isn't appealable. The companies have announced their intent to appeal to the Federal Circuit.

The Supreme Court has three petitions pending in its docket that are also challenging Fintiv. They had hit

a wall at the Federal Circuit over the same institution decision hurdle as the California case.

Fintiv critics say the AIA guarantees the right to petition the PTAB regardless of what's happening in district court and that trials are often pushed beyond the date relied on by the PTAB.

Addy said the pushback is more of a political move from Big Tech companies than anything else, as they're upset the PTAB isn't invalidating as many patents as it had in the past.

"When I read a lot of what the anti-Fintiv side is saying, a lot of it has assumptions in it like, 'You can't let these bad patents stand.' But we don't know if they're bad patents until they're adjudicated," she said. "It's really a political maneuver to try and rein in the PTAB, which has become less one-sided."

The cases are *Apple Inc. et al. v. Hirshfeld*, case number 5:20-cv-06128, in the U.S. District Court for the Northern District of California, and *Apple Inc. v. Optis Cellular Technology LLC, et al.*, case number 21-118, *Mylan Laboratories Ltd.v. Janssen Pharmaceutica NV et al.*, case number 21-202, and *Intel Corp. v. VLSI Technology LLC*, case number 21-888, in the Supreme Court of the United States.

GlaxoSmithKline v. Teva

At the circuit court level, the Federal Circuit is in the process of deciding whether the full court should take up an induced infringement case. The dispute is over whether Teva induced doctors to infringe a patent for one indication of GlaxoSmithKline's cardiovascular drug Coreg, which it was cleared to sell as a generic for other non-patent-protected uses. Generic drugs that carve out patent-protected indications feature so-called skinny labels.

A split Federal Circuit panel in 2020 found that Teva did induce infringement. After an outcry from the generic industry claiming the court undermined the entire skinny label practice, the original panel agreed to rehear the case. It reached the same conclusion in August, but said the ruling was more tailored to the specific GSK-Teva debate. Teva's en banc petition argues that there is still a broad implication that needs to be reined in.

"Even with the narrowing decision we got from the panel, there's a precedential Federal Circuit decision that says when you have a carveout, you can be subject to litigation and that you can be held liable for this," said Laura Lydigsen of Crowell & Moring LLP, who largely works with generic-drug companies. "The clean line is when you have a proper carveout, the generic shouldn't be liable."

The case is *GlaxoSmithKline LLC v. Teva Pharmaceuticals USA Inc.*, case number 18-1976, in the U.S. Court of Appeals for the Federal Circuit.

Amgen v. Sanofi

The Supreme Court is reviewing a petition filed by Amgen in a case that has captured the attention of the biologics world.

In a win for Sanofi and Regeneron Pharmaceuticals Inc., the Federal Circuit in February held that a patent covering Amgen's cholesterol medication Repatha wasn't enabled — meaning a person skilled in the art couldn't figure out the bounds of the patent without undue experimentation.

Amgen is asking whether enablement is a question of law to be decided by a judge or a question of fact

to be decided by a jury. While a jury had upheld the patent, judges have overridden that ruling.

The petition also asks whether enablement requires someone skilled in the art to "make and use" the claimed invention.

Amgen's patent covers a genus of antibodies that bind to a protein called PCSK9 and features 26 examples of amino acid sequences that bind to PCSK9. The case has large implications for antibody-based biologics because it upped the scrutiny on how many examples are needed to justify the patent being enabled.

"When you're thinking about a very, very large genus of possible molecules, you get into this question [of], 'Are 85 positive candidates sufficient to enable that entire genus when you've really only shown what the structure for two of them are?'" said Richard Emmons of Withers. "There's no bright-line rule on this, and it's something that — for those of us who are drafting applications — we worry about a lot because you don't want to end up in this situation."

The case is *Amgen Inc. et al. v. Sanofi et al.*, case number 21-757, before the Supreme Court of the United States.

--Editing by Alanna Weissman.